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Testimony Presented by
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Ways and Means Subcommittee on Health
On

"Payment, Safety and Quality Issues in Treatment of Patients with ESRD"

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Mr. Chairman, Members of the Ways & Means Subcommittee on Health and invited guests, I want to thank you for holding this hearing today on a very important issue - patient safety and quality of care for Medicare beneficiaries with End Stage Renal Disease (ESRD), a devastating chronic and debilitating illness. My remarks today will be concise and will focus on three key areas: (1) health disparities in ESRD, (2) the need to be cautious and judicious when considering any changes to Medicare ESRD reimbursement; particularly bundling separately billable services into the composite rate and major changes to the existing CMS Erythropoietin Monitoring Policy, and (3) the need for prevention of ESRD given the massive tidal wave of baby boomers that will soon enter the ranks of the Medicare program.

As a Member of Congress representing a district with significant incidence of Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD), I am deeply concerned about the rapidly increasing numbers of patients on dialysis in my district as well as the United States overall. Each year CKD, a progressive condition that impairs kidney function, kills more than 14 people out of every 100,000, making it the nation's ninth leading cause of death.

There are approximately 470,000 people with ESRD, with 330,000 being treated with dialysis under Medicare in the United States today. Almost all ESRD patients –93%-- are Medicare eligible creating a significant role for the Federal government in managing the care and expenditures for this very vulnerable and sick patient population. We have an obligation to Medicare beneficiaries with ESRD to ensure they receive the best available care.

As many of you may know, CKD and ESRD strikes people of all ages and races; however, it disproportionately affects minority populations, including African Americans, Hispanics, American Indians and Asians. Let me give you some statistics to convey the seriousness of this disease for communities of color. African Americans are 3.8 times more likely to suffer kidney failure than whites; for Native Americans, the rate is 2.0 times greater; and for Asian/Pacific Islander Americans, the rate is 1.3 times greater. The risk of kidney failure for Hispanics versus non-Hispanics is 1.5 times greater than the rate for whites.

For African Americans, who are susceptible to risk factors such as hypertension, diabetes, and obesity, and who may contend with socioeconomic factors that limit their access to health care services, the burden of CKD is disproportionately high.

Although African Americans only make up approximately 13% of the overall U.S. population, they represent approximately 38% of all patients treated for ESRD in the United States. African Americans also suffer kidney failure at an earlier age than their white counterparts: in 2006, the mean age for African Americans at the start of treatment for kidney failure was 56.4 years, compared with 59.6 for white Americans.

The leading causes of ESRD in the African American population are diabetes and hypertension. Diabetes, the leading cause, represents approximately 43% of all new cases each year. African Americans represented nearly one-third of new patients whose kidney failure was caused by diabetes.

The prevalence of diabetes has reached nearly epidemic levels in the African American community: 2.7 million (11.4%) of all African Americans, aged 20 or older, have diabetes; one third of these cases are undiagnosed. This phenomenon is reflected in the steadily rising incidence rate of diabetic ESRD among African Americans: African Americans with diabetes have 6 times the risk of kidney failure, in comparison with whites. Over the last decade, for Americans younger than age 40, the rates of diabetic ESRD have decreased among white Americans, but have increased among African Americans.

The second leading cause of ESRD – hypertension – affects one in every three African Americans. In African Americans under the age of 40, the rates of kidney failure caused by hypertension has increased over the last decade, while the rates of their white counterparts have decreased. Overall, African Americans

comprise 51% of new patients whose kidney failure was attributed to hypertension.

African American men ages 20 to 29 are 10 times more likely to develop kidney failure due to high blood pressure than white men in the same group; African American men ages 30 to 39 are approximately 14 times more likely to develop kidney failure due to high blood pressure than their white counterparts. Overall, rates of ESRD attributed to hypertension are up to 16 times greater in African Americans than white Americans.

The fact that these precursors to CKD are so prevalent in the African American community and in the family histories of most African Americans underscores the notion that all African Americans may be at risk and further heightens the importance of increased awareness, prevention, and screening among this population.

As a physician and Member of the Congressional Black Caucus, I am compelled to protect and ensure that correct policy choices are being made so that minority patients with ESRD who suffer from this terrible disease have access to the highest quality patient care.

In my testimony today I would like to comment on the policy proposal of quickly establishing a fully bundled payment system for ESRD – that is to bundle ESRD medications and other separately billable services into the composite payment rate. My concern is that patients on dialysis fall along a diverse spectrum of care and have distinct needs. This is especially true of African Americans who have more co-morbidities like diabetes, hypertension and obesity which impact dosing requirements. According to the Kidney Care Partners (KCP) African-Americans have a low response rate to anemia management therapy. These patients require higher doses of erythropoietin. According to KCP:

“A significant percentage of ESRD patients have a low response rate to anemia management therapy and, therefore, require higher doses of erythropoietin stimulating agents (ESAs) to achieve clinical performance targets. Thus, patient variability can be a major factor leading to variations in comparative data...the particular clinical needs of key patient groups, such as African Americans, can require higher levels of ESAs in order to generate red blood cell development.”

These differences among patients make it difficult to predict an average treatment regimen along a wide range of services and highly variable dosage of ESRD related medications. I want to urge my esteemed colleagues on this Committee that we must exercise extreme caution as we consider any policy changes so we don't affect patient care.

Additionally, we must be careful that ESRD payment policy changes do not adversely impact small dialysis organizations creating an access issue for many communities, but especially in the inner cities. This is a real concern in the African American community.

As the Medicare Payment Advisory Commission (MedPAC) suggested in their March 2007 report there are potential treatment access issues for African Americans. Many of the dialysis facilities that closed in 2005 treated a greater proportion of African Americans than facilities that opened (48 percent vs. 29 percent).

As the Chairman knows, the MMA required that CMS undertake a demonstration project that would examine the feasibility of bundling all dialysis services into one composite rate. During the December Ways and Means Hearing, we heard testimony from CMS about the difficulty of establishing an appropriate case mix adjuster—the tool needed to ensure that patient variation is adequately addressed in developing a bundled payment.

I am sure CMS can attest to the challenges that still exist in developing a fully bundled payment system. I am dedicated to developing a payment system that works well, provides the best quality care for Medicare beneficiaries, and strongly believe that any change should be tested first to understand the implications.

Ensuring that minority patients with ESRD have access to dialysis facilities and receive high quality patient care is one of my top priorities. Recently, CMS announced that it was reviewing the EMP, in light of the FDA's recent issuance of new warnings regarding Erythropoiesis Stimulating Agents (ESAs). I'm concerned that changes to the EMP, which has now been in effect for one year, could negatively impact minority patients. I do not want to see a repeat of the devastating effects that payment changes in ESRD had on patients in 1997, when CMS (HCFA at the time) issued the original Hematocrit Measurement Audit Program Memorandum (HMA-PM). That policy limited the ability of physicians to treat anemia and resulted in poor quality outcomes. The policy was subsequently changed and improved considerably after stakeholders voiced concerns. The current policy – the Erythropoietin Monitoring Policy was updated again in 2006, as a result of a thoughtful and transparent process with renal community input. Given the massive implications for patient care, any changes to the EMP should not be done in an arbitrary manner. CMS should establish an open and transparent process to allow external experts and stakeholders to consider the potential impact revisions would have on patient care. Further, Congress should not legislate a policy change on the EMP that CMS and the renal community have effectively been collaborating on for years.

We must be good stewards of taxpayers dollars, but instead of considering policies that may compromise care for some of Medicare's most

vulnerable patients, we should be looking at policies that emphasize disease prevention. Prevention of major medical conditions is of paramount importance for public health in the United States because of the increasing prevalence of conditions such as obesity, diabetes and heart disease... the very conditions that contribute to the onset of CKD. In light of the growing population eligible for Medicare and the baby boomers soon to come, we must look for policy solutions to keep Medicare beneficiaries healthy and avoid costly treatments instead of rationing care for patients after the onset of disease. As stewards of the Medicare program we must do what is best for Medicare patients first and foremost rather than letting raw economics make these determinations.

Mr. Chairman and Congressman Camp, as the costs of healthcare continues to skyrocket, I know the temptation is to do something quickly and the easiest and quickest approach is to cut costs. That is the kind of knee-jerk reaction that is not worthy of this institution. More importantly it runs the very real and very high risk of hurting patients. And because such a large proportion of the patients with ESRD are African Americans, we again will be the ones most adversely impacted by decisions made without careful study of all of the clinical implications. We should have learned that lesson in 1997.

I would hope – and the Congressional Black Caucus and all of our partnering organizations, universities and advocacy groups are working hard at it– that we could get you our colleagues and leaders on the issue of health to see that the only way to cut costs is to emphasize prevention and increase the portion of the health budget dedicated to it; and to eliminate the disparities in health - a major one of which is ESRD - that cause people of color to seek care that is often uncompensated at late stages of disease. This is the only way to really reduce health care costs.

Cost containment runs the real risk of exacerbating an already-unjust, inequitable and ineffective system of healthcare in this country where some Americans – usually those that look like me – are left behind or left out period.

I thank the Chairman for holding this hearing so we may learn more about this important issue and hope that we focus on what is best for chronically ill ESRD patients.